

WHAT IS CLAIMED IS:

1. A method for calibrating a clinical laboratory analytical instrument, comprising:
generating control pool data from a commutable control pool, wherein the control
pools have target analyte values for an assay;
5 generating patient specimen data from a distribution of test values from patient
specimens;
determining tolerance limits from the control pool data and the patient specimen data;
and
adjusting the calibration of the instrument with respect to the tolerance limits.
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2. The method of claim 1, further comprising reducing variation in the patient specimen
data prior to determination of the tolerance limits.
3. The method of claim 1, further comprising tracking the normalized distribution of the
15 patient specimen data prior to determination of the tolerance limits.
4. The method of claim 2, further comprising tracking the normalized distribution of the
patient specimen data prior to determination of the tolerance limits.
- 20 5. The method of claim 1, wherein the tolerance limits comprise at least one of warning
limits and action limits.
6. The method of claim 1, wherein the adjusting step comprises generating a calibration
control signal.
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7. A method for calibrating a clinical laboratory instrument, comprising:
(a) generating a serum control rule by:
(i) providing a control pool that is commutable with patient specimen data
for a particular target analyte used in an assay, and
30 (ii) determining traceable target analyte values for the control pool;
(b) generating a patient distribution index by:

- (i) reducing variation in a patient distribution, and
- (ii) tracking normalized patient test values;
- (c) determining tolerance limits for the maximum allowable variation of the serum control rule and the patient distribution index;
- 5 (d) comparing the patient distribution index and the serum control rule to detect a bias with respect to the tolerance limits; and
- (e) adjusting the calibration of the analytical instrument to modify the bias.

8. A computer readable medium encoded with a computer program, the program being
10 arranged such that, when the program is executed, a computer performs the acts of:

- generating control pool data from a commutable control pool, wherein the control pools have target analyte values for an assay;
- generating patient specimen data from a distribution of test values from patient specimens;
- 15 determining tolerance limits from the control pool data and the patient specimen data;
- and
- adjusting the calibration of the instrument with respect to the tolerance limits.

9. The program of claim 8, further comprising reducing variation in the patient
20 specimen data prior to determination of the tolerance limits.

10. The program of claim 8, further comprising tracking the normalized distribution of the patient specimen data prior to determination of the tolerance limits.

25 11. The program of claim 10, further comprising tracking the normalized distribution of the patient specimen data prior to determination of the tolerance limits.

12. The program of claim 8, wherein the tolerance limits comprise at least one of warning limits and action limits.

13. The program of claim 8, wherein the adjusting step comprises generating of a calibration control signal.

14. The program of claim 8, further comprising generating an advisory with the calibration control signal.

15. The program of claim 8, further comprising determining the efficacy of the calibration adjustment procedure with respect to the tolerance limits.

16. The program of claim 15, wherein the determination comprises calculating the residual RMS error with respect to the tolerance limits.

17. A chemical analyzer comprising a processor responsive to a computer program, the program being arranged such that, when the program is executed, the processor performs the acts of:

generating control pool data from a commutable control pool, wherein the control pools have target analyte values for an assay;

generating patient specimen data from a distribution of test values from patient specimens;

determining tolerance limits from the control pool data and the patient specimen data;

and

adjusting the calibration of the instrument with respect to the tolerance limits.

18. The analyzer of claim 17, further comprising reducing variation in the patient specimen data prior to determination of the tolerance limits.

19. The analyzer of claim 19, further comprising tracking the normalized distribution of the patient specimen data prior to determination of the tolerance limits.

20. The analyzer of claim 19, further comprising tracking the normalized distribution of the patient specimen data prior to determination of the tolerance limits.

21. The analyzer of claim 17, wherein the tolerance limits comprise at least one of warning limits and action limits.

5 22. The analyzer of claim 17, wherein the adjusting step comprises generating of a calibration control signal.

23. The analyzer of claim 17, further comprising generating an advisory with the calibration control signal.

10 24. The analyzer of claim 17, further comprising determining the efficacy of the calibration adjustment procedure with respect to the tolerance limits.

15 25. The analyzer of claim 24, wherein the determination comprises calculating the residual RMS error with respect to the tolerance limits.

20 26. A clinical analytical instrumentation system, comprising a central computer and a network of chemical analyzers, wherein at least one of the central computer and the analyzers comprise a processor responsive to a computer program, the program being arranged such that, when the program is executed, the processor performs the acts of:

generating control pool data from a commutable control pool, wherein the control pools have target analyte values for an assay;

generating patient specimen data from a distribution of test values from patient specimens;

25 determining tolerance limits from the control pool data and the patient specimen data; and

adjusting the calibration of the instrument with respect to the tolerance limits.

30 27. A method for analyzing data in an analytical laboratory, wherein the laboratory comprises a central computer networked with at least one chemical analyzer, the method comprising:

transferring assay data from the analyzers to the central computer, wherein a processor in the central computer:

generates control pool data from a commutable control pool, wherein the control pools have target analyte values for an assay;

5 generates patient specimen data from a distribution of test values from patient specimens;

determines tolerance limits from the control pool data and the patient specimen data; and

10 adjusts the calibration of at least one chemical analyzer with respect to the tolerance limits.

28. A method for calibrating a clinical laboratory analytical instrument, comprising:

generating a serum control rule from a commutable control pool, wherein the control pools have target analyte values for an assay;

15 generating a patient distribution index from patient specimens;

determining tolerance limits from the serum control pool and the patient distribution index; and

adjusting the calibration of the instrument with respect to the tolerance limits.